

REMARKS

Applicant respectfully requests reconsideration. Claims 1-2, 4-5, 9, 11, 42-50 and 52-54 were previously pending in this application. By this amendment, Applicant is canceling claim 50 without prejudice or disclaimer. Claim 1 has been amended. New claim 55 has been added. As a result, claims 1-2, 4-5, 9, 11, 42-50 and 52-55 are pending for examination. No new matter has been added.

Claim 1 was amended to remove the reference to HLA-A2.1; this feature is now recited in new claim 55. Claim 1 also was amended to incorporate the features recited in claim 50; claim 50 has been canceled.

Rejection Under 35 U.S.C. 112, First Paragraph

The Examiner maintained the rejection of claims 1, 2, 4, 5, 9, 11, 42-50 and 52-54 as not enabled by the specification. Applicant respectfully traverses the rejection.

The Examiner cites two reasons for asserting that a person of ordinary skill in the art would not know how to use the claimed invention for cancer treatment and diagnosis: (1) that one cannot predict that SEQ ID NO:1 is adequately expressed on cancer cells compared to normal control tissue, and (2) the unpredictability of cancer diagnosis and treatment. (Office Action at pages 3-4).

The Examiner is inappropriately basing the enablement rejection on one possible use for the claimed invention, which use the Examiner has selected from among the several possible uses. In fact, the Examiner acknowledges that Applicant has asserted that there are other uses for the claimed invention, yet the Examiner continues to base the rejection solely on one specific use. Other uses asserted by the Applicant are not addressed in any way in the Examiner's

argument; accordingly Applicant respectfully traverses and requests reconsideration of the rejection on at least this basis.

Although additional uses are not considered in the rejection, the Examiner acknowledged at page 4, lines 6-9 of the Office Action that there are other uses asserted in the specification:

“Further, it is not clear what other use is applicable for the claimed genus of MAGE-10 peptides, or nonapeptides, as asserted in the response, besides the contemplation in the specification of making antibodies or CTLs for diagnosis of or treating diseases caused by SEQ ID NO:1, or cancer.” (Emphasis added)

The use of the peptides for producing antibodies and CTLs, and the use of such antibodies and CTLs, is clearly described in the specification, for example at page 6, lines 11-22, page 7, lines 16-23, and page 9, line 26 to page 13, line 30. In addition, Example 5 shows that allogeneic tumor cell lines derived from two different melanoma patients, which cell lines were shown to express MAGE-A10, are recognized by the CTLs provided in the application (CTL 447A/5).

The Examiner asserted that one reason for the alleged lack of enablement of the claims is that “One cannot predict that SEQ ID NO:1 is adequately expressed on primary cancer cells as compared to normal control tissues....” Office Action at page 3. Regarding the predictability of expression, Applicant notes that the peptides were isolated based on recognition by a CTL clone from a melanoma patient, which means that MAGE-A10 protein must have been expressed and one or more peptides presented by the patient’s immune system. Applicant does not agree that the prior art cited by the Examiner on page 3 would cause the person of ordinary skill in the art to use undue experimentation in making and/or using the claimed invention. Nor does Applicant agree that the results of Example 5 cannot be correlated with expression of MAGE-A10 on primary tumor tissue. The subject from whom the CTL clone was isolated had a primary tumor, melanoma. The CTLs recognize presented peptides from the expressed MAGE-A10 protein; given that MAGE-A10 is not expressed in normal tissues, normal tissues would not have produced the MAGE-A10 protein. Therefore, even given the teachings in the art, one skilled in the art would recognize that the data in the specification support that MAGE-A10 is in fact expressed on primary tumor tissues. The RT-PCR data found in Example 6 support and confirm

that view. Any *further* confirmation of the expression of MAGE-A10 on primary tumors could be done with routine experimentation, such as by immunohistochemistry or other antibody-based detection method, which are very well known in the art.

The Examiner asserted that another reason for the alleged lack of enablement of the claims is "The unpredictability of cancer diagnosis and treatment" in the prior art previously cited. Office Action at page 4. Regarding this alleged unpredictability, Applicant respectfully notes that the claims do not require cancer diagnosis or treatment. Therefore, any unpredictability of cancer diagnosis and treatment is irrelevant to the claimed peptides.

What is relevant is whether the teachings of the specification permit one of ordinary skill in the art to practice the claimed isolated polypeptides and nonapeptides of defined sequence. Given the knowledge of the person of ordinary skill in the art, the high level of skill in this art, the working examples provided, the descriptive guidance in the specification and the reasonable breadth of the claims, Applicant submits that the skilled person would not have to exercise undue experimentation in practicing the claimed invention.

Moreover, the Examiner has not addressed Applicant's prior argument regarding the lack of undue experimentation required to make and use the claimed invention. Specifically, Applicant previously argued:

"...Applicant notes that the Examiner's assertion does not adequately take into consideration the fact that any experimentation needed is entirely routine for the person of ordinary skill in this art. Moreover, the specification provides more than adequate guidance to make and/or use the claimed invention. Testing a finite and well-defined set of polypeptides for HLA-A2 binding and/or CTL stimulation is not require an exercise of undue experimentation; it is simply routine experimentation in this art."

"Finally, Applicant reiterates that the claimed invention is directed to isolated polypeptides that have uses other than the use singled out by the Examiner. Preparation of the claimed polypeptides, given the sequences and experimental guidance provided in the specification, would not require undue experimentation by the skilled person. Indeed, such preparation is entirely routine in the art, as evidenced by the long history of tumor rejection antigen peptides that is mentioned in the background section of the specification on pages 1-3."

Amendment filed March 29, 2007, at pages 7-8.

Similarly, preparation of antibodies, CTLs, etc. as described in the application would not require an undue amount of experimentation, at least because of the extensive description in the application providing guidance to the skilled person, the knowledge of the person of skill in the art regarding the preparation of peptides, antibodies and CTLs, the high level of skill in this art, the working examples provided, and the reasonable breadth of the claims.

Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of the claims as not enabled.

Rejection Under 35 U.S.C. 112, Second Paragraph

The Examiner rejected claims 1, 44-46 and 50-54 as being indefinite. Applicant respectfully requests reconsideration of the rejection.

Applicant has amended claim 1 to remove the reference to HLA-A2.1. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of the claims as indefinite.

Rejection Under 35 U.S.C. 102(b)

The Examiner rejected claims 1-2 and 52-54 as being anticipated by Townsend et al. (WO/9525740-A1). Applicant respectfully requests reconsideration of the rejection.

Applicant has amended claim 1 to incorporate the features of claim 50. The two additional peptides referenced in claim 1 as being excluded from the claim are the peptides described in Townsend et al. Therefore, claim 1 as amended does not include the Townsend et al. peptides.

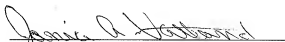
Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1-2 and 52-54 as being anticipated by Townsend et al. (WO/9525740-A1).

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



Janice A. Vatland, Ph.D.
Reg. No. 52,318
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
Telephone: (617) 646-8000

Docket No. L0461.70115US00

Date: September 14, 2007

X09/14/07X